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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	PAPER NUMBER
3762	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/671,329	BLAYA ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. It is initially noted that the Examiner partly disagrees with the Applicant as to the substance of the interview on 6 April 2009. In the interview, per the Summary and per page 9, lines 21-23, it was suggested that all independent claims be amended with both a limitation for "computer-controlled modulation" and a limitation for "updating at least three times." Additionally, regarding the applied art, it was only agreed upon that is both amendments were made to each of the independent claims, then only the Beard reference as applied would be overcome. No stance regarding the other rejections was agreed upon pending further search and consideration based on the amendments.

2. Applicant's arguments, see page 10, paragraphs 2-3, filed 8 May 2009, with respect to the rejection of claims 19-23 and 32 under 35 U.S.C. §101 have been fully considered and are persuasive. The §101 rejection of claims 19-23 and 32 has been withdrawn.

3. Although Applicant presents no arguments directed specifically at either of Grim'661 or Kelly'948, the rejections under 35 U.S.C. §102(b) based in each is considered to be overcome by way of amendment to the claims and are herein withdrawn. Neither of Grim'661 or Kelly'948 discloses computer-controlled actuation.

4. Applicant's remaining arguments filed 8 May 2009 have been fully considered but they are either not persuasive or are moot in view of new grounds of rejection. Claims 37 and 39 stand rejected under 35 U.S.C. 102(b) as being anticipated by Beard'296. Claims 24 and 33-36 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated

by Stein'332. Claims 1-9, 11-23, 25-29, 32 and 37-40 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johnson'693. Claims 1-4, 6-8, 11-23, 25-30, 32 and 37-40 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Horst'882. Claim 41 stands rejected under 35 U.S.C. 102(e) as being clearly anticipated by Goffer (US 2003/0093021, hereinafter Goffer'021). Claims 6-8 stand rejected under 35 U.S.C. 103(a) as obvious over Beard'296.

5. Applicant generally states that the amendments of computer-driven actuation and updating at least three times during a walk cycle would not read on any of the references of record. It is noted that claims 37-41 were not amended to recite the latter of updating at least three times during a walk cycle, and therefore are not considered to be part of this argument. Insomuch as each of the maintained references clearly recites computer-controlled actuation as further explained herein below, each of claims 37-41 remain rejected for the previously cited reasons.

6. Regarding claims 1-36, which were amended to include both computer-controlled actuation and updating at least three times during a walk cycle, it is noted that each of the applied references has been agreed to disclose updating at least twice during a walk cycle.

For those references wherein only two updates per cycle are disclosed (Beard'296, Swain757, Goffer'021), it is considered obvious to update a third time during the cycle as it merely constitutes a repetition of an updating step, wherein a repetition of steps in a known process involves only routine skill in the art. For those same references, each is considered to disclose an adaptive control, and therefore is

considered to still apply to claims 37-41 as previously applied since such claims were not amended to further clarify that adaptive control specifically relies on updating at least three times during a walking cycle.

Regarding Stein'332, three levels of stimulation, i.e. updating at least three times during each walk cycle, is clearly shown in Figure 5.

Regarding Johnson'693, the previously cited section at column 9, lines 3-27 clearly recites a 5-state adaptive control, which clearly reads on the limitation of at least three updates.

Regarding Horst'882, the reference discloses a three-phase control in column 5 line 63 through column 6 line 27 which clearly reads on the limitation of updating at least three times per cycle.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 37 and 39 stand rejected under 35 U.S.C. 102(b) as being anticipated by Beard et al. (US Patent 5,112,296, hereinafter Beard'296).

Regarding claim 37, Beard'296 discloses a variable-impedance active ankle foot orthosis (title; abstract; column 3, lines 5-40; column 4, lines 20-25; column 5, lines 50-60) comprising an actuator coupled to a foot portion of the orthosis (Fig. 1, actuator 10; column 4, lines 1-5 and 25-30; column 5, lines 1-48) for modulating a joint stiffness or damping of an ankle joint at least twice during each walking cycle for treating an ankle foot gait pathology, wherein the pathology comprises drop foot (abstract; column 5, lines 38-60). It is noted that there is inherently a joint formed between the leg portion 4 and foot portion 2. Alternatively, the knee orthotic joint 8 can also be considered to anticipate the claims as written, since it is not specified that the joint be the ankle joint, but rather that the joint be related to treatment of an ankle foot gait pathology. Specifically regarding the amended limitation for computer-controlled actuation, Beard'296 shows computer control circuit in Figure 7.

Regarding claim 39, Beard'296 discloses a method of modulating joint stiffness or damping of an ankle joint of an orthosis at least twice during each walking cycle (abstract) wherein the method includes adjusting the stiffness of the joint during controlled plantar flexion and minimizing impedance during late stance (column 1, lines 20-36; column 2, lines 10-67; column 5, lines 47-60). It is noted that the joint between the leg portion and foot portion inherently exists and is inherently modulated throughout gait. It is also noted that the impedance of the knee orthotic joint is modulated throughout the walking cycle, and therefore anticipated the claims. Specifically regarding the amended limitation for computer-controlled actuation, Beard'296 shows computer control circuit in Figure 7.

9. Claims 24 and 33-36 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stein (US Patent 5,643,332, hereinafter referred to as Stein'332).

Stein'332 clearly outlines a FES stimulation device and method which modulates ankle stiffness during the swing phase of a walking cycle, which inherently provides control during controlled plantar flexion and minimizes forefoot collision. Regarding the newly submitted claim limitation of modulation during swing phase, reference is specifically made to column 6, lines 34-55.

Regarding the amended limitation for computer-controlled actuation, Stein'332 discloses computer controlled actuation in Figure 4 and in column 6, lines 14-25.

Regarding the amended limitation that the modulation occur in an updating manner at least three times during each walk cycle, Stein'332 shows three stimulation levels, i.e. three updates, in Figure 5.

10. Claims 1-9, 11-23, 25-29, 32 and 37-40 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johnson et al. (US 5,662,693, hereinafter Johnson'693).

Particular emphasis is placed on the abstract; Figures 1, 3c, 5 and 9; column 8, lines 4-14; column 9, lines 3-27; column 10, lines 55-65.

Specifically regarding claim 5, the actuator shown in Figure 3c of Johnson'693 can be considered a series elastic actuator.

Regarding the amended limitation for computer-controlled actuation, Johnson'693 discloses such in column 8, lines 15-34 and column 9, lines 4-27.

Regarding the amended limitation that the updating occur at least three times during each walk cycle, Johnson'693 clearly discloses a 5-state actuation in Figure 11 and in column 9, lines 3-27.

11. Claims 1-4, 6-8, 11-23, 25-30, 32 and 37-40 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Horst (US 6,966,882, hereinafter Horst'882).

Particular emphasis is given to the abstract, Figures 1 and 4-6 and related paragraphs, particularly as pertains to assist, monitor, and rehabilitate modes 508-512 to address the adaptive nature of the modulation.

Horst'882 discloses computer-controlled actuation in column 3, lines 41-58.

Horst'882 discloses updating at least three times per walk cycle in column 5, line 63 through column 6, line 28.

12. Claim 41 stands rejected under 35 U.S.C. 102(e) as being clearly anticipated by Goffer (US 2003/0093021, hereinafter Goffer'021).

Emphasis is placed on paragraphs [3], [6], [220], [221], [225] and [226] which describe a method of treating an ankle foot gait pathology using functional electrical stimulation in conjunction with a traditional orthosis or brace.

Goffer'021 discloses computer-controlled actuation in paragraph [51] and adaptive modulation in the abstract and paragraph [3].

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1, 2, 4, 10, 11, 19, 20, 22, 29 and 30 are rejected, and claims 6-8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Beard'296.

Regarding claims 1, 4 and 10, Beard'296 discloses a variable-impedance active ankle foot orthosis (title; abstract; column 3, lines 5-40; column 4, lines 20-25; column 5, lines 50-60) comprising an actuator coupled to a foot portion of the orthosis (Fig. 1, actuator 10; column 4, lines 1-5 and 25-30; column 5, lines 1-48) for modulating a joint stiffness or damping of an ankle joint at least twice during each walking cycle for treating an ankle foot gait pathology, wherein the pathology comprises drop foot (abstract; column 5, lines 38-60). It is noted that there is inherently a joint formed between the leg portion 4 and foot portion 2. Alternatively, the knee orthotic joint 8 can also be considered to anticipate the claims as written, since it is not specified that the joint be the ankle joint, but rather that the joint be related to treatment of an ankle foot gait pathology. Specifically regarding the amended limitation for computer-controlled actuation, Beard'296 shows computer control circuit in Figure 7.

Regarding claims 19, 20 and 22, Beard'296 discloses a method of modulating joint stiffness or damping of an ankle joint of an orthosis at least twice during each walking cycle (abstract) wherein the method includes adjusting the stiffness of the joint

during controlled plantar flexion and minimizing impedance during late stance (column 1, lines 20-36; column 2, lines 10-67; column 5, lines 47-60). It is noted that the joint between the leg portion and foot portion inherently exists and is inherently modulated throughout gait. It is also noted that the impedance of the knee orthotic joint is modulated throughout the walking cycle, and therefore anticipated the claims.

Further regarding claims 1 and 19, Beard'296 is considered to disclose the invention substantially as claimed including adaptive and updating control of joint stiffness or damping, but does not expressly disclose that the updating occurs at least three times during each walk cycle. It would have been obvious to one of ordinary skill in the art at the time of the invention it to update a third time during the cycle as it merely constitutes a repetition of an updating step, wherein a repetition of steps in a known process involves only routine skill in the art.

Regarding claim 2, Beard'296 discloses a torsional spring stiffness control and spring-damper positional control (Fig. 6; column 5, lines 1-48). It is also noted that the actuator controls the stiffness of the knee orthotic joint.

Regarding claims 6 and 8, Beard'296 discloses an angle sensor (Fig. 4, radial resistor 24; column 4, lines 60-68; column 6, lines 18-36) capable of being used on the ankle. Furthermore, since a knee angle inherently has a correlated and consistent ankle angle during the standing phase, measuring the angle of the knee is synonymous with measuring the correlated ankle angle. In the alternative, angle sensors are well known in the art, such as those described in Beard'296, Stein'332 and Horst (US Patent 6,966,882, hereinafter referred to as Horst'882), all of which are capable of being used

on the ankle of a patient suffering drop foot. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Beard'296 device to monitor the ankle rather than the knee, because the knee angle is an equivalent measurement to the ankle angle in the control sense as discussed above.

Regarding claims 7 and 8, Beard'296 discloses EMG sensors which function as ground reaction force sensors (column 4, lines 50-60; column 5, line 59 through column 6, line 18). At foot strike, the musculature of the leg intuitively reacts to the impact by increasing stimulation to the leg stabilizer muscles in order to absorb the force of the impact and balance the patient while walking. Thus, impact ground force is transferred quantifiably to contractions of the leg musculature that is being sensed by the EMG electrodes of the Beard'296 device. In the alternative, ground reaction force sensors (or foot switches) are well known in the foot orthosis art and are described in Horst'882, Swain et al., and Naft et al. (US Patent 6,517,503). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Beard'296 with a ground reaction force sensor as described in the prior art cited above to provide the Beard'296 system with an accurate means of distinguishing the varying stages of the walking cycle to more accurately time activation of the orthosis to prevent the symptoms of drop foot.

Regarding claim 11, a drop foot patient inherently has one or both of anterior or posterior muscle weakness. Therefore, the Beard'296 device inherently treats a patient having such conditions.

Regarding claims 29 and 30, the spring disclosed in Beard et al is considered to be operatively coupled to the orthotic joint both at the ankle and to the knee orthotic joint (4). Beard'296 also discloses sensing one or more parameters or the orthotic joint (column 4, lines 60-68)

15. Claim 9 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Beard'296 in view of Swain et al. or in view of Naft et al. (US Patent 6,517,503).

Regarding claim 9, Beard'296 discloses the invention substantially as claimed but does not expressly discloses a foot switch. In the same field of endeavor, Swain et al. teaches the use of a foot switch for sensing foot rise or foot strike in order to accurately deliver stimulation for treatment of drop foot (abstract). Additionally in the same field of endeavor, Naft et al. teaches use of a foot switch in an external orthosis device to selectively lock and unlock the knee joint in order to provide improved gait (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Beard'296 with the foot switch of either Swain et al. or Naft et al. to provide the Beard'296 system with the same advantage of improving patient gait and treating drop foot (motivation to combine provided by the abstracts of Swain et al. and Naft et al.).

16. Claims 24 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swain et al. (US Patent 6,507,757).

Regarding claim 24 Swain et al. clearly discloses the invention as claimed (Figs. 1-6; abstract; column 2, lines 16-67; column 12, line 10 through column 14, line 10). Regarding the limitation of modulation during swing phase, reference is specifically

made to column 1, lines 16-37; column 12, lines 27-43; and column 13, lines 3-50. Regarding the limitation for computer-controlled actuation, Swain clearly shows a control unit 40 in Figure 6.

Swain is considered to disclose the claimed invention except that the updating occur at least three times during each walk cycle. It would have been obvious to one of ordinary skill in the art at the time of the invention it to update a third time during the cycle as it merely constitutes a repetition of an updating step, wherein a repetition of steps in a known process involves only routine skill in the art.

17. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goffer (US 2003/0093021, hereinafter Goffer'021).

Emphasis is placed on paragraphs [3], [6], [220], [221], [225] and [226] which describe a method of treating an ankle foot gait pathology using functional electrical stimulation in conjunction with a traditional orthosis or brace. Goffer'021 discloses computer-controlled actuation in paragraph [51] and adaptive modulation in the abstract and paragraph [3].

Goffer'021 discloses the invention substantially as claimed, but does not expressly disclose that the updating occurs at least three times per walk cycle. . It would have been obvious to one of ordinary skill in the art at the time of the invention it to update a third time during the cycle as it merely constitutes a repetition of an updating step, wherein a repetition of steps in a known process involves only routine skill in the art.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

6 November 2009

/George Manuel/
Primary Examiner